

No. 05- 05 - 682 NOV 25 2005

IN THE OFFICE OF THE CLERK
Supreme Court of the United States

JACK McMULLEN and BARBARA McMULLEN,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In May of 2000, Jack McMullen was implanted bilaterally with deep brain neurostimulation devices developed and manufactured by Defendant Medtronic, Inc., (Medtronic) for the treatment of the symptoms of Parkinson's disease. In 1997 Medtronic had been granted a Premarket Approval (PMA) by the Food and Drug Administration (FDA) for unilateral implantation. At the time Mr. McMullen received his bilateral implant devices, Medtronic was applying for a PMA supplement for bilateral implants. Such approval was granted January 14, 2002.

Regulations issued by the Food and Drug Administration required Medtronic to track each of these devices to the patient and to keep contact information regarding each patient so that patient could be quickly contacted should Medtronic become aware of unanticipated adverse events with the devices. In January of 2001, Medtronic became aware that exposure of recipients of these deep brain neurostimulation implant systems to radiofrequency diathermy (a common experience of daily life) could result in severe injury or death. Pursuant to FDA regulations, device manufacturers were permitted to issue warnings to recipients of its devices about subsequently discovered dangers without prior FDA approval pursuant to 21 CFR 814.39(d)(1).

In March of 2001, Jack McMullen, not having been warned of the danger of exposure to radiofrequency diathermy, underwent a radiofrequency diathermy treatment, as part of a routine dental procedure, which resulted in severe injury. On May 18, 2001, Medtronic, by ordinary mail, sent a Safety Alert (without any prior FDA authorization) to recipients of its deep brain neurostimulation devices warning of the danger of severe injury or death from the exposure to diathermy.

The Following Questions are Presented

1. Does Premarket Approval of Class III Medical Devices under the Medical Device Act justify the sweeping preemption holdings of several federal circuit courts that bar virtually all state common law actions regarding those devices?

2. Are state common law causes of actions for violation of a manufacturer's post-sale duty to timely warn of dangers of serious injury or death, once such dangers become known to the manufacturer, preempted by the Medical Device Act (MDA)?

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| 1. Review is warranted to resolve the conflict among the circuit courts and various state courts regarding the preemptive effect of the MDA on state common law causes of action. Due to the widely varying interpretation of the Court's decision in <i>Lohr v. Medtronic, Inc.</i> by lower courts, this is an issue on which this Court's guidance is urgently needed. | 10 |
| 2. Review of this case is essential to determine whether Medtronic's post-sale duty to warn of new dangers to patients with Class III medical devices is preempted by FDA approval of those devices, and whether that approval absolves | |

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| Medtronic of any continuing duty to warn of new and serious dangers of which it becomes aware after the devices are implanted in the patients. | 15 |
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OPINIONS BELOW

The United States Court of Appeals for the Seventh Circuit is reported at *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005). The Seventh Circuit issued its decision and opinion on August 26, 2005. The Seventh Circuit affirmed the September 15, 2004 order of the United States District Court granting Medtronic's motion for summary judgment and denying plaintiffs' motion for summary judgment. (See Appendices A and B).

STATEMENT OF JURISDICTION

On December 5, 2002, Jack McMullen, and his wife, Barbara McMullen, filed their Complaint against Medtronic, Inc. ("Medtronic") in the Vermillion County Indiana Circuit Court. This action was removed to the United States District Court for the Southern District of Indiana by Medtronic on the basis of diversity of citizenship under 28 U.S.C. § 1332. The Plaintiffs, Jack McMullen and Barbara McMullen, are citizens of the State of Indiana. Defendant Medtronic is a corporation incorporated under the laws of the State of Minnesota and maintains its principal place of business in the State of Minnesota. The amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00). Jurisdiction in the district court was further based on original jurisdiction under 28 U.S.C. §§ 1331 and 1337.

On September 16, 2004, the district court granted Medtronic's motion for summary judgment. The McMullen's appealed from that final judgment to the Seventh Circuit Court of Appeals. Jurisdiction in the circuit court of appeals was based on 28 U.S.C. § 1291. The circuit court of appeals issued its opinion and order affirming the district court's granting of summary judgment in favor of Medtronic on August 26, 2005.

This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

**CONSTITUTIONAL, STATUTORY AND
REGULATORY PROVISIONS INVOLVED**

Title 21 United States Code Section 360(k)

State and local requirements respecting devices

(A) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter

**21 Code of Federal Regulations, Section
§ 801.1(d)**

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local

requirements applicable to the device different from, or in addition to the specific [FDA] requirements

**21 Code of Federal Regulations, Section 821.1
Scope**

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug and Cosmetic Act (the act) which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and the FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences. . . .

(b) these regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient.

Effective tracking of devices . . . is necessary for the effectiveness of remedies prescribed by the act, such as patient notification. . . .

**21 Code of Federal Regulations, Section
814.39(d)**

Section (d)(1) of 21 CFR 814.39 states:

After FDA approves a PMA, any change described in Paragraph (d)(2) of this section that enhances the safety of the device or the safety in the use of the device may be placed into effect by the

applicant prior to the receipt under Sec. 814.17 of a written FDA order approving the PMA supplement. . . .

Section (2) states, in pertinent part:

The following changes are permitted by paragraph (d) (1) of this section:

(i) Labeling changes that add or strengthen a contraindication, warning, precaution or information about an adverse reaction. (SA p.49)

STATEMENT OF THE CASE

On July 31, 1997, Medtronic, Inc. ("Medtronic"), a leading manufacturer of implantable medical devices, received United States Food and Drug Administration ("FDA") Premarket Approval (PMA) of its application to market a unilateral deep brain stimulation system under the trade name of the "Medtronic Activa Tremor Control System." This was a unilateral deep brain stimulation implant system for the treatment of the symptoms of Parkinson's Disease. An explicit condition of the FDA'S approval of Medtronic's unilateral Activa Tremor Control system provided:

Under Section 519(e) of the Act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final users or patient so that the devices can be located quickly if serious problems are occurring with the products.

Following this approval, with its tracking requirement for the Activa Tremor Control system, Medtronic filed a